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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,457	01/21/2005	Eric Ferrandis	427.094	5578
47888 7590 05/23/2007 HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 05/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/522,457

Applicant(s)

FERRANDIS ET AL.

Examiner

Anne M. Gussow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 2-6 are pending and under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains NEW GROUNDS of rejections.

### ***Objections Withdrawn***

4. The objection to the specification is withdrawn in view of applicant's amendments.

### ***Response to Arguments/NEW GROUNDS of REJECTIONS***

5. The rejection of claims 2-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out how the 90kD protein was determined is maintained.

The response filed March 8, 2007 has been carefully considered but is deemed not to be persuasive. The response states "the molecular weight determination was made under the standard denaturing and reducing conditions". In response to this argument, applicant is required to include this limitation in the recitation of the claims, as stated in the prior office action. "When a molecular weight is recited to characterize a protein the claims should include not only the method by which it was determined, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were used" (see Office

Action page 3). Therefore, the description of the 90kD protein is indefinite and the rejection is maintained.

***Priority***

6. The foreign priority claim filed on March 8, 2007 was not entered because the foreign priority claim was not filed during the time period set forth in 37 CFR 1.55(a)(1). For original applications filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the time period is during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. For applications that have entered national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT. See 37 CFR 1.55(a)(1)(ii). If applicant desires priority under 35 U.S.C. 119(a)-(d), (f) or 365(a) based upon a prior foreign application, applicant must file a petition for an unintentionally delayed priority claim (37 CFR 1.55(c)). The petition must be accompanied by (1) the claim (i.e., the claim required by 35 U.S.C. 119(a)-(d) and (f) and 37 CFR 1.55) for priority to the prior foreign application, unless previously submitted; (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.55(a)(1) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

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should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

The request to amend the priority of the instant application has been denied because applicant has not filed a petition to amend the priority of the application and a certified copy of the priority document FR01/02631 has not been received.

Additionally, the certified copy of the priority document FR 02/10560 was not accompanied by an English translation of the priority document. To receive priority a certified English translation is necessary, therefore the priority date of the pending claims is August 25, 2003.

### ***Specification***

7. The disclosure is objected to because of the following informalities:

a.) the specification has been amended to claim priority to a foreign patent application, however, priority to the application has not been granted (see priority above).

b.) in the brief description of the figures, the description of figure 4 does not include a description of figure 4A.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. Claims 2-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of treating cancer dependent on growth factor GHRH in warm-blooded animals comprising administering to warm-blooded animals in need thereof an amount of an isolated protein obtained by extraction of *Pilocarpus Heterophyllus*, said protein having a molecular mass of approximately 90.9 kDa and comprises fragments of peptide sequences SEQ ID No. 1, SEQ ID No. 2, and SEQ ID No. 3 and being able to be presented in a glycosylated or non-glycosylated form sufficient to treat said cancer.

The specification as-filed does not provide adequate written description support as to the method of extraction of the 90.9 kDa protein. One of skill in the art would not be able to distinguish between the instant 90.9 kDa protein and any other 90.9 kDa protein that contains the small 6-14 amino acid peptides of SEQ ID Nos. 1-3. The claims do not provide method steps as to the extraction of the protein from the plant species. The molecular weight of a protein can change dependent upon the method of extraction.

Thus, the isolated protein is not defined. The skilled artisan cannot envision the detailed structure of the encompassed polypeptides included in a 90.9 kDa protein

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comprising fragments of peptide sequences SEQ ID Nos. 1-3 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

9. The rejection of Claims 2-6 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained. The response filed March 8, 2007 has been carefully considered but is deemed not to be persuasive. The response states that "utility has been demonstrated" (see response page 4). In response to this argument, the use of the protein meets the test of substantial and credible utility, as supported by the as-filed specification and the supporting evidence in applicant's amendment (see response page 4 and graph), however, as broadly claimed does not meet the standards for enablement. The response also states that one skilled in the art would know what type of cancers are dependent upon growth factor GHRH (see response page 4). In response to this argument, the lack of enablement was not directed to the determination of GHRH cancers, but the isolation of a protein from a plant species (*Pilocarpus Heterophyllus*) effective to treat those cancers. The protein in the claimed method is described by molecular weight (90.9 kDa), and small peptide fragments obtained by extraction. As claimed, one of skill in the art would not know what extraction method would result in isolation of the same protein. Saravanan and Rose (Proteomics, 2004. Vol. 4, pages 2522-2532) compare extraction of plant proteins using phenol or acetone.

Saravanan and Rose teach that the methods generated different protein yields (table 1), different patterns of bands in one-dimensional gel electrophoresis (figure 2 and page 2526 1<sup>st</sup> column) and different two-dimensional gel electrophoresis protein spot patterns (figure 3 and page 2526 2<sup>nd</sup> column). Thus, due to the lack of guidance provided and the unpredictability of the art as cited above and in the prior office action, the rejection is maintained.

### ***Conclusion***

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

May 9, 2007



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER